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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/647,458      | 08/01/2003  | Sophie Chen          | CSO-0001-P          | 2036             |

23413 7590 12/23/2005

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| EXAMINER |
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DELACROIX MUIRHEI, CYBILLE

|          |              |
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| ART UNIT | PAPER NUMBER |
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1614

DATE MAILED: 12/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |   |                                     |  |
|------------------------------|---|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/647,458          | <b>Applicant(s)</b><br>CHEN, SOPHIE |  |
|                              | <b>Examiner</b><br>Cybille Delacroix-Muirheid | <b>Art Unit</b><br>1614             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

Due to the complex nature of the claims, no request for an oral election is being made.

Please see MPEP 812.01.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-39, drawn to methods of treating cancer and compositions, classified in class 514, subclass 451, 456.
- II. Claims 40-43, drawn to a method for treating estrogen-related disorders, classified in class 514, subclass 451, 456.

The inventions are distinct, each from the other because of the following reasons:

The inventions listed in Groups I-II are independent and distinct. The invention of Group I is directed to a method of treating cancer in a patient as well as compositions for treating cancer; the invention of Group II is directed to a method of treating estrogen-related disorders. Each method has a separate and distinct outcome from the expected outcome of the other methods. For example, the expected result of a method of treating cancer (Group I) is distinctly different from a method of treating an estrogen-related disorder (Group II) such as osteoporosis (claim 41), since the desired outcome of treating cancer is to arrest abnormal proliferation and metastatic spread of cancerous cells, whereas the desired outcome of treating an estrogen-related disorder, for example, osteoporosis, is to alleviate or even reverse bone loss.

Additionally, each of the methods would be practiced in a distinctly different population of patients. While there may be incidental overlap in the groups of patients experiencing, for example, cancer and those experiencing, for example osteoporosis, the therapeutic objective,

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endpoints and steps required to treat such dissimilar conditions are vastly different and do not reasonably suggest the treatment of the other. Finally, composition claims 29-39 contain, in addition to the claimed phytoestrogens, an additional anti-cancer agent (claim 29) or an additional anti-cancer agent and an immune stimulant (claim 36). Thus, these compositions are required in the cancer treatment methods, which are materially different processes than treating estrogen related disorders. The composition claims are grouped accordingly with claims 1-28.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: SPECIES (1) drawn to the wogonin compound of formula (1); SPECIES (2) drawn to the isoliquiritigenin compound of formula (2); SPECIES (3) drawn to the coumestrol compound of formula (3); and SPECIES (4) drawn to the prenyl isoflavonoid compound of formula (4).

With respect to Group II, the patentably distinct species comprise the specific estrogen-related disorders set forth in claim 41.

The compounds represented by SPECIES (1)-(4) are structurally and chemically distinct and the search for one compound would not necessarily result in a comprehensive search of the other compounds. Moreover, examination of the generic claims 40-41 in Group II in their entirety would constitute an undue burden on the Examiner due to the disparate nature of the diseases and disorders that are within the scope of these claims. The distinct nature of the claimed species is supported by the fact that each disease or disorder has a different etiology and

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pathophysiological manifestation and that each is treated differently. Such is sufficient to indicate that each disease listed above is differently searched in the patent and non-patent literature and that a search for one disease will not necessarily result in a comprehensive search of any one or more of the other diseases listed. Despite the fact that applicant may have established an underlying commonality for the claimed diseases, i.e. they are estrogen-related diseases, it remains that each of the diseases is recognized in the art as being clinically and pathophysiologicaly distinct from one another and, thus, each of the above-identified species is capable of supporting separate patents.

If Group I is elected, applicant must elect one of SPECIES (1)-(4).

If Group II is elected, applicant must elect one of SPECIES (1)-(4), since claim 40, refers to "one or more of the foregoing compounds." Additionally, applicant must elect a single disorder from the group of specific disorders described in claim 41.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 22, 29, 36, 40 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybill Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*CM*

*Dec. 14, 2005*

*Cybil*  
Cybille Delacroix-Muirheid  
Patent Examiner Group 1600